



**EPA**

## Fact Sheet

### **Availability of External Peer Review Draft of "Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization Based on Emerging Information"**

The external review draft (ERD) of the document entitled *Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization* was completed December 31, 1998. The document, developed by the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), will undergo external expert review by ten independent scientists on February 10 and 11, 1999 in San Bernardino, California and subsequently will be revised based on the results of the peer review. The draft presents an updated human health risk assessment as well as an ecological assessment of newly performed studies on the toxicity of perchlorate. Its development is part of a wider interagency effort to address environmental contamination issues related to perchlorate. The purpose of this document is to provide scientific support and rationale for hazard identification and dose-response assessments based on the emerging data for both human health and ecological effects caused by exposure to perchlorate. It is not intended to be a comprehensive study on the chemical or toxicological nature of perchlorate.

A Federal Register Notice announcing the external peer review meeting and the availability of the draft document was published on January 14, 1999 (64 FR 2492). For any further information on the upcoming peer review meeting, refer to the Office of Ground Water and Drinking Water's website at <http://www.epa.gov/ogwdw/ccl/perchlor/perchlo.html>.

#### ***What is perchlorate?***

Perchlorate ( $\text{ClO}_4^-$ ) is an anion that exists as a contaminant in ground and surface waters from the solid salts of ammonium, potassium, magnesium or sodium perchlorate. Perchlorate is very mobile in aqueous systems and can persist for many decades under typical ground and surface water conditions. Subsequent to the development of a new chemical analytic detection methodology in April 1997, which can detect perchlorate at levels of four parts per billion (ppb) and above, perchlorate has been measured at various manufacturing sites and in well water and drinking water supplies. There are currently 14 states with confirmed releases in ground or surface water. There are 44 states with confirmed perchlorate manufacturers or users based on EPA Information Request responses.

#### ***What are possible sources of contamination?***

Sources for the contamination include some chemical fertilizer and various other chemical and industrial uses. One major source of contamination is the manufacture of ammonium perchlorate for use as the oxidizer component and primary ingredient in solid propellant for rockets, missiles, and fireworks. Large-scale production began in the United States in the mid-1940s. Because of its shelf life, it must be periodically washed out of the country's missile and rocket

inventory and replaced with a fresh supply. Thus, large volumes of the compound have been disposed of in California and likely other states, since the 1950s. Perchlorate salts are also used on a large scale as a component of air bag inflators.

### ***What are concerns regarding exposure to perchlorate?***

Potassium perchlorate was used previously in the United States to treat hyperthyroidism resulting from an autoimmune condition known as Graves' disease. Potassium perchlorate is still used diagnostically to test thyroid hormone levels in some clinical settings. The basis for the effect on thyroid hormone function is the competitive inhibition of iodide anion uptake by the thyroid which results in reduced thyroid hormone production. Thyroid hormone deficiencies can affect normal metabolism, growth and development. Disruption of the thyroid hormone homeostasis can also result in the formation of thyroid tumors, particularly in rodents.

Perchlorate is of concern because of: 1) existing uncertainties in the toxicological database to adequately address the potential for perchlorate to produce human health/ecotoxicological effects at low levels in drinking water; 2) uncertainties regarding the extent of the occurrence of perchlorate in ground and surface waters; 3) the efficacy of different treatment technologies for various water uses; and 4) the extent and nature of ecological impact or transport and transformation phenomena in various environmental media.

At this time there has not been a systematic national survey of perchlorate occurrence. This represents a key data gap in the ability to characterize risk. There is no National Primary Drinking Water Regulation (NPDWR) for perchlorate. Perchlorate was placed on the Office of Water's Contaminant Candidate List in March 1998, and noted that it requires additional research and information before regulatory determinations can be made.

### ***What information is contained in the Perchlorate ERD?***

This ERD presents an updated human health risk assessment as well as an ecological assessment of newly performed studies on the toxicity of perchlorate. The human health risk assessment model harmonizes noncancer and cancer approaches to derive a single oral risk benchmark based on precursor effects for both neurodevelopmental effects and thyroid neoplasia. Both of these are historically established effects of disturbances in the hypothalamic-pituitary-thyroid feedback system. The oral risk benchmark (RfD), as proposed, is protective of potential cancer because of new perchlorate data on the lack of genotoxicity and the reversibility of thyroid hyperplasia. These data allowed perchlorate to be characterized as an indirect anti-thyroid chemical according to current EPA guidance (see Assessment of Thyroid Follicular Cell Tumors at <http://www.epa.gov/ncea/thyroid.htm>). The proposed oral benchmark is 0.0009mg/kg-day. This value reflects the inclusion of a composite uncertainty factor of 100, although some reviewers

The harmonized RfD is an oral risk benchmark estimate of the amount of perchlorate, which when ingested daily over a lifetime is anticipated to be without adverse health effects (both noncancer and cancer) to humans, including sensitive subpopulations. At the RfD or below, exposures are expected to be safe.

suggested that an uncertainty factor of at least 300 would be more consistent with the available data. Although presented as a point estimate, a benchmark value such as this is typically considered to be an average estimate with uncertainty ranging from 3-fold below to 3-fold above. The confidence in the derivation is medium. If standard default body weight (70 kg) and water consumption (2 L/day) values were applied to the benchmark value to derive an action level, the resulting value (32 ppb) would be slightly above the current range of action levels (4 to 18 ppb) based on the previous provisional RfD values. Assessment of ecological screening data suggest that additional research is warranted. The human and ecological assessments may be used in the future to support development of a health advisory or NPDWR and cleanup decisions at hazardous waste sites. No systematic survey of perchlorate occurrence or exposure characterization has yet been made and represents a key data gap in the ability to characterize risk.

The development of the ERD and the risk assessment activities regarding perchlorate have been a model for a full and open public process involving several EPA offices, programs, and regions, other Federal Agencies, States, and the industry and the public. Of particular note is the Interagency Perchlorate Steering Committee (IPSC), a working partnership of government agencies chartered to facilitate identification of the issues and coordinate the exchange of scientific information related to potential perchlorate contamination in the environment. The IPSC currently includes representatives from the EPA, Department of Defense, Agency for Toxic Substances and Disease Registry, National Institute for Environmental Health Sciences, National Aeronautics and Space Administration, Bureau of Indian Affairs, Arizona Department of Environmental Quality, Arizona Department of Health Services, California Department of Health Services, Nevada Division of Environmental Protection, Texas Natural Resource Conservation Commission, Utah Department of Environmental Quality, Utah Department of Health Laboratories, Cocopah Tribe, Colorado River Indian Tribes, Fort Mojave Tribe, Chemehuevi Tribe, and Quechan Tribe.

#### ***How do you get a copy of the draft document?***

The draft document can be downloaded from the NCEA website at <http://www.epa.gov/ncea/perch.htm>. Copies of the document, as well as all supporting information, will be available for review at the following locations: EPA Regional Office Superfund Records Centers; EPA Headquarters Information Resources Center, Washington, DC; NCEA Offices in Cincinnati, OH and Research Triangle Park, NC; California Department of Health Services; California Environmental Protection Agency's Office of Environmental Health Hazard Assessment; and the Operation Toxicology Branch at Wright-Patterson Air Force Base, Dayton, OH.

#### ***EPA Scientific/Technical Contact:***

Annie M. Jarabek, NCEA, ORD (MD-52) , RTP, NC 27711

E-Mail: [jarabek.annie@epa.gov](mailto:jarabek.annie@epa.gov)

Tel: 919-541-4847; FAX: 919-541-1818